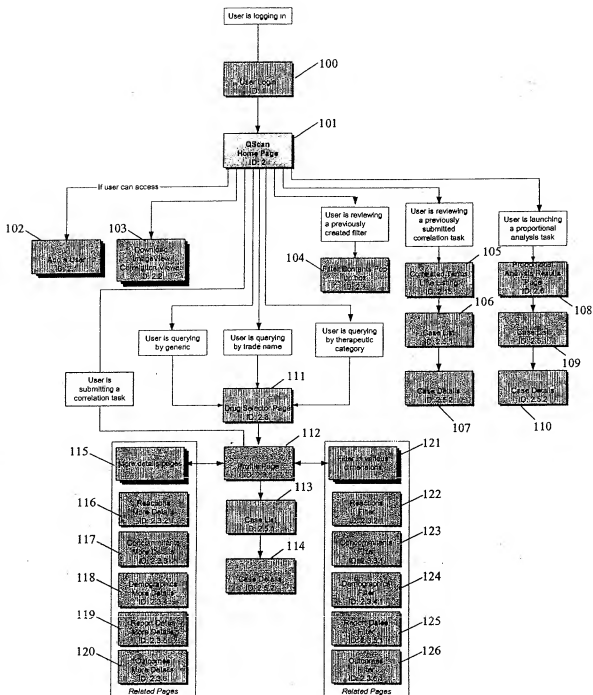


### Figure 1



**Figure 2**

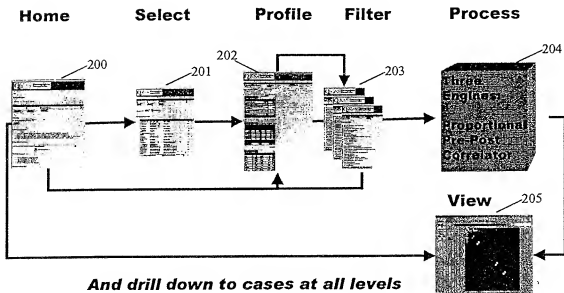


Figure 3

The screenshot displays the QSCAN Pharmacovigilance Selector/Profiler interface. At the top, the title 'QSCAN Pharmacovigilance Selector/Profiler' is shown. Below the title, there is a 'home' link and a 'Data source: FDA SRS/AERS Combined Data' label. The main section contains three input fields: 'Generic Name:', 'Trade Name:', and 'Therapeutic category:'. Each field has a dropdown menu with 'SELECT' and 'RESET' buttons. Below these fields, there is a 'Filtering:' section with a 'Saved filter:' dropdown and buttons for 'Select', 'OK', and 'Cancel'. The 'AEM Engine/notes:' section lists two entries: '[delete] [Dec 22, 2000 9:44:45 PM] Completed correlation task # 13: AMLODIPINE BESYLATE view results...' and '[delete] [Dec 22, 2000 6:28:17 PM] Completed correlation task # 14: CANDESARTAN CILEXETIL view results...'. The 'Proportional analyses:' section includes a 'Compute for therapeutic category:' dropdown set to 'Ace Inhibitors', a 'GO' button, and checkboxes for 'Bayesian Rating' and 'Compare only with therapeutic category'. The 'Administrative tasks:' section at the bottom includes links for 'Add New User', 'Logout', and 'Download the ImageView 1.1.4.1 Correlation viewer (1.3 MB)'.

home 301

Selector/Profiler: Data source: FDA SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

SELECT RESET SELECT

Filtering:

Saved filter: Select OK Cancel

302

303

AEM Engine/notes:

- [delete] [Dec 22, 2000 9:44:45 PM] Completed correlation task # 13: AMLODIPINE BESYLATE view results...
- [delete] [Dec 22, 2000 6:28:17 PM] Completed correlation task # 14: CANDESARTAN CILEXETIL view results...

304

Proportional analyses:

Compute for therapeutic category: Ace Inhibitors

GO ☒ Bayesian Rating ☐ Compare only with therapeutic category

Administrative tasks:

- Add New User
- Logout
- Download the ImageView 1.1.4.1 Correlation viewer (1.3 MB)

Figure 4

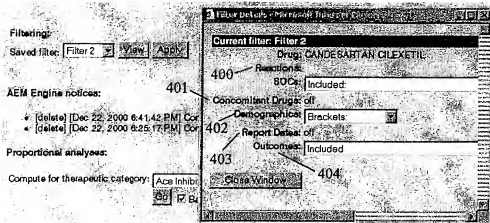


Figure 5

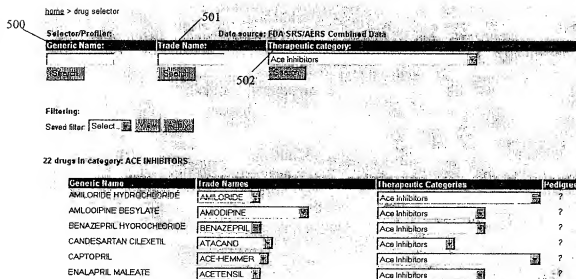


Figure 6

Data Pedigree							
Map To	Verbatim	Source	Incidents	Case Count	QEDRx Processing	Cross-reference	First/Last Reported Reactions
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1999/Dec 2 1997
PROZAC	Prozac	AERS	3378	3308 S		Orange Book	Nov 1 1997/Jun 29 1999
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		NDCC Tradename	Jan 1 1979/Oct 14 1997
FLUOXETINE	Fluoxetine	AERS	574	571 S		NDCC Tradename	Nov 1 1997/Jun 18 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378		M Orange Book	Nov 1 1997/Jun 12 1999
PROZAC	Prozac (Fluoxetine)	AERS	140	140		M Orange Book	Nov 7 1997/Apr 24 1999
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122 S		Orange Book	Nov 14 1997/Jun 27 1999
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	65	65		M Orange Book	Mar 1 1998/Jun 24 1999
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20		M Orange Book	Nov 1 1997/Mar 12 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17		M Orange Book	
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15		M Orange Book	Nov 15 1997/Jun 5 1999

Figure 7

700

701

702

703

704

Reactions		
	View	HLT (256 of 1495)
		filter
Top 10 HLTs of 256	Reaction Count	% of Reactions
Hypertension and increased blood pressure NEC	68	3.88%
General symptoms and signs NEC	57	3.25%
Disturbances in consciousness	52	2.97%
Renal function analyses	46	2.63%
Headaches NEC	46	2.63%
Cardiac function diagnostic procedures	46	2.63%
Neurological signs and symptoms NEC	45	2.57%
Nausea and vomiting (all forms)	43	2.45%
Asthenic conditions	43	2.45%
Vascular tests NEC including blood pressure	42	2.40%
	Top 10 HLTs	Total reactions
	488	1752
	more details...	

Figure 8

Concomitant Drugs 801 802 filter

		Non-Suspect		Suspect		Total		%
Top 10 drugs		S	NS	S	NS	Total	Total	
HYDROCHLOROTHIAZIDE	9	36	0	0	45	10.79%		
ASPIRIN	2	38	0	5	45	10.79%		
FUROSEMIDE	2	32	0	1	35	8.39%		
DIGOXIN	0	30	0	0	30	7.19%		
AMLODIPINE BESYLATE	0	24	4	0	28	6.71%		
ENALAPRIL MALEATE	4	15	0	5	24	5.76%		
VERAPAMIL HYDROCHLORIDE	11	10	0	2	23	5.52%		
ESTROGENS, CONJUGATED	0	23	0	0	23	5.52%		
METOPROLOL SUCCINATE	8	11	0	3	22	5.28%		
METOPROLOL TARTRATE	0	15	0	7	22	5.28%		
		Non-Suspect		Suspect		Total		
		Total	Total	Total	Total	Total	Total	
		172	1141	1313				

more details...

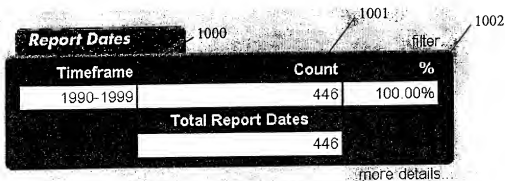
Figure 9

Demographics 900 901 filter

Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
51-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details...

**Figure 10**



**Figure 11**

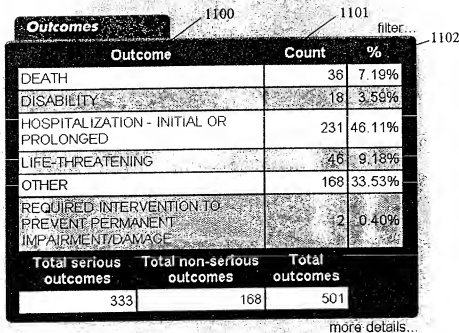




Figure 12

Reactions | Drugs | Outcomes | Report Sources | Timeframes | Demographics | Cases | Filter Notes

deafness

Reactions

- ☒ blood and lymphatic system disorders
- ☒ cardiac disorders
- ☒ congenital and familial/inheritable disorders
- ☒ ear and labyrinth disorders
- ☒ external ear disorders (exc. congenital)
- ☒ hearing disorders
- ☒ deafness and hyperacusis
  - ☒ deafness, conductive (exc. otosclerosis)
  - ☐ deafness, neurosensory
  - ☐ deafness, permanent
  - ☒ deafness, transient
  - ☒ dysacusis
  - ☒ hearing impaired
  - ☐ hearing impairment aggravated
  - ☒ hyperacusis
  - ☒ hypoacusis
  - ☐ presbycusis
- ☒ inner ear and eighth cranial nerve disorders
- ☒ middle ear disorders (exc. congenital)
- ☒ miscellaneous ear disorders
- ☒ endocrine disorders
- ☒ eye disorders
- ☒ gastrointestinal disorders

Generate profile for this filter (This Filter has not been profiled)

Figure 13

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Task 95) View with ImageView

[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7706	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7861	Renal function analyses	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paresis (exc congenital and cranial nerve)	Other Reaction	Central nervous system hemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
6	6286	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5869	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

Figure 14

## Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

Cases 1 to 18 of 18 cases

Cases 1 to 18 of 18 cases			1402	1403	1404	1405	1406	1407	1408
Case ID	Sex	Manufacturer Control Code	FDA Report Recpt Date	Age	Drugs	Reactions	Serious		
1	3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N	
2	3198047	F	19990200143	1999-03-12	57	Acuretic, Atorvastatin, Atacand, Cefixime, Nitro-Dur, Terbesmin, Expectorante	Blood Creatinine Increased; Blood Urea Increased; Hypotension NOS; Renal Failure Acute	Y	
3	3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Cletalin, Antivert, Pyridium, Zolof, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased; Coronary Artery Disease Nos; Hemoptysis, Heart Rate Increased, Hypertension Aggravated, Renal Failure Acute	N	
4	3270258	F	19990400493	1999-06-26	75	Atacand, Hydrochlorothiazide	Arrhythmia; Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression; Electrocardiogram U Wave Appearance; Electrolyte Imbalance; Hypochloremia; Hypokalemia; Hyponatremia; Loss Of Consciousness Nec; Renal Impairment Nos; Syncope	N	

Figure 15

## Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Case for term pair: Renal function analyses (Other Reaction) / Renal failure and impairment (Other Reaction)

1501	Case ID:	3198047				
1502	Sex:					
1503	Age:	57.0 years, 0.0 months				
1504	Reactions:	As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class
		Blood Creatinine Increased	Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Blood Urea Increased	Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders
		Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (excluding nephropathies)	Renal and urinary disorders
1505	Concomitant Drugs:	Name	Dose	Route	Suspect Status	
		Acuretic	TAB QD		Yes	
		Atorvastatin			No	
		Atacand	16 MG QD PO ORAL		Yes	
		Cefixime			No	
		Nitro-Dur			No	
		Tierbasmin Expectorante			No	
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (HO) LIFE-THREATENING(LT)				
1507	Manufacturer Control Code:	19990200143				
1508	Manufacturer Date:	1999-03-5				
1509	Adverse Event Date:	1998-12-13				
1510	Report Type:	EXP				
1511	Report Source:	OTH				
1512	Case Source:	AERS				
1513	Narrative:					

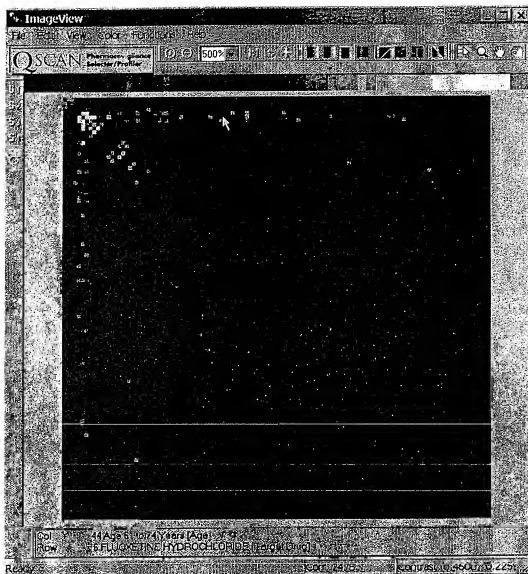
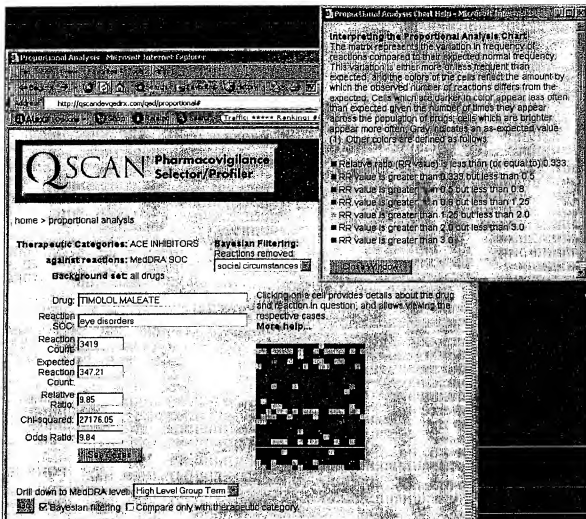
**Figure 16**

Figure 17



# Figure 18

**Proportional Analysis**  
 [ACE INHIBITORS] vs. Reactions (SOCs)  
 View by HLGTS

1800	Drug:	AMLODIPINE BESYLATE
1801	Reaction:	Surgical and medical procedures
1802	Reaction Count:	927
1803	Expected Reaction Count:	201.02
1804	Relative Ratio:	4.61
		See Cases

# Figure 19

550 entries for this analysis are displayed below:

Correlated Terms		1900	1901	1902	1903	1904
[Reaction]	[Drug]	[Count]	[Expected Count]	[Relative Ratio]		
1 6: Eye disorders	19: TIMOLOL MALEATE	3392	346.3	9.8		
2 24: Surgical and medical procedures	2: AMLODIPINE BESYLATE	1732	200.4	8.6		
3 14: Metabolism and nutrition disorders	1: AMLODIPINE HYDROCHLORIDE	838	266.5	3.1		
4 24: Surgical and medical procedures	13: METHYLDOPA	37	15.6	2.4		
5 16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE	65	28.6	2.3		
6 4: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL	32	14.3	2.2		
7 24: Surgical and medical procedures	20: TRANDOLAPRIL	13	6	2.2		
8 14: Metabolism and nutrition disorders	18: SPIRONOLACTONE	1330	616.1	2.2		

### Figure 20

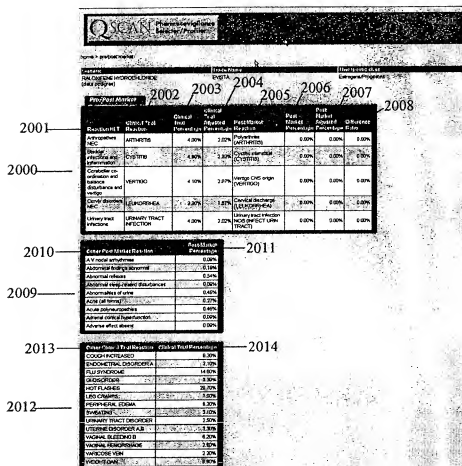


Figure 21

